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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/772,815	01/30/2001	Patrick S.L. Wong	ARC 2958R1	1011
7590	03/17/2004		EXAMINER	
ALZA Corporation 1900 Charleston Rd. P.O. Box 7210 Mountain View, CA 94043-7210			REDDICK, MARIE L	
		ART UNIT	PAPER NUMBER	
		1713		

DATE MAILED: 03/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/772,815	WONG ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Judy M. Reddick	1713	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) Responsive to communication(s) filed on 02 December 2003.  
 2a) This action is FINAL.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) Claim(s) 9 and 16-19 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 9 and 16-19 is/are rejected.  
 7) Claim(s) 9 and 16 is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

**Continued Examination Under 37 CFR 1.114**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/02/03 has been entered.

**Claim Objections**

2. Claims 9 and 16 are objected to because of the following informalities: In claims 9 & 16, it is suggested that "additive(s)" be used in lieu of "additives" so as to establish antecedent basis for "one additive". Appropriate correction is required.

**Claim Rejections - 35 USC § 112**

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 9 and 16-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recited "between 1-60 cc.ml/cm<sup>2</sup>.hr" per claim 9 constitutes indefinite as per the hyphen(-) engendering an inconsistency with the modifier "between". It is suggested that "and" be used in lieu of the hyphen(-).

**Claim Rejections - 35 USC § 102**

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 9 and 16-18 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Manjikian(Re. 27,280), Riley(U.S. 3,648,845), Theeuwes(U.S. 3,760,984, as applied to claims 9 & 16-18), Eckenhoff et al(U.S. 4,320,758, as applied to claims 9 and 16-18) or Friesen et al(U.S. 4,883,593).

**Manjikian** discloses processes for producing a semipermeable membrane by casting such membrane from a solution comprising (a) a cellulosic derivative such as cellulose acetate-butyrate and ethyl cellulose, (b) a flux promoter, (c) a water-soluble organic solvent for the cellulose derivative and (d) pyridine. See the Abstract, col. 1, lines 30-72, col. 2, lines 4, 42 & 50-72, col. 3, lines 1-75, the Runs, col. 7, lines 19-34 and the claims of Manjikian and the instant claims 9, 16 and 17.

**Riley** teaches ultra thin semipermeable membranes made from film-forming polymeric organic materials such as cellulose esters and derivatives thereof that include cellulose acetate-butyrate and cellulose ethers such as ethyl cellulose. See the Abstract, col. 2, lines 48-75 and col. 3, lines 1-9, col. 5, lines 15-70 and Run 1 of Riley and the instant claims 9, 16 and 17.

**Theeuwes** teaches semipermeable membranes derived from materials that include cellulose acetate propionate and cellulose acetate butyrate. See, col. 3, lines 39-47, the paragraph bridging cols. 4-5, col. 8, line 42, col. 9, line 55, col. 10, lines 1-15 of Theeuwes and the instant claims 9 and 16-18.

**Eckenhoff et al** teach a shape retaining, semipermeable membrane derived from cellulose acetate butyrate and other shape-retaining semipermeable membranes

including those disclosed in Theeuwes such as cellulose acetate propionate(U.S. 3,760,984, incorporated by reference). See, col. 2, lines 10-18 & 68, col. 3, lines 56-68, col. 4, lines 1-7, col. 5, lines 17-24 and 61-66 and col. 6, lines 37-43 of Eckenhoff et al and the instant claims 9 and 16-18.

Friesen et al teach semipermeable membranes formed from cellulosic materials which include cellulose acetate butyrate. See the Abstract, col. 1, lines 47-64 and the claims of Friesen et al and the instant claims 9, 16 and 17.

Each of Manjikian, Riley, Theeuwes, Eckenhoff et al and Friesen et al therefore anticipate the instantly claimed invention with the understanding that the semipermeable membrane of each of Manjikian, Riley, Theeuwes, Eckenhoff et al and Friesen et al overlap in scope with the instantly claimed semipermeable membrane.

As to the "water transmission" property per claims 9 and 16, it would be expected that the semipermeable membranes of each of Manjikian, Riley, Theeuwes, Eckenhoff et al and Friesen et al would meet this property limitation since the semipermeable membranes of each of Manjikian, Riley, Theeuwes, Eckenhoff et al and Friesen et al are essentially the same as and made in essentially the same manner as the claimed semipermeable membrane. The onus to prove otherwise is shifted to applicants.

It has been held that where applicant claims a composition in terms of function, property or characteristic where said function is not explicitly shown by the reference and where the examiner has explained why the function, property or characteristic is considered inherent in the prior art, it is appropriate for the examiner to make a rejection under both the applicable section of 35 USC 102 and 35 USC 103 such that the burden is placed upon the applicant to provide clear evidence that the respective compositions do in fact differ. *In re Best*, 195 USPQ 430, 433 (CCPA 1977); *In re Fitzgerald et al.*, 205 USPQ 594, 596 (CCPA 1980).

Even if it turns out that the Examiner has somehow missed the boat and the claims are not anticipated then, it would have been obvious to the skilled artisan to extrapolate,

from the disclosures of each of Manjikian, Riley, Theeuwes, Eckenhoff et al and Friesen et al, the specifically defined semipermeable membrane, as claimed, as per such having been within the purview of the general disclosures of each of patentees and with a reasonable expectation of success, absent a showing of some unusual or unexpected results.

As to the recited “for use in a dosage form” per claim 9, such is considered to be a statement of ultimate intended utility. Moreover, the absence of a disclosure relating to a function does not defeat a finding of anticipation. It is well established that the recitation of a new intended use for an old product does not make a claim to that old product as provided for under the guise of *In re Schreiber*, 128 F 3d 1473, 1477, 44 USPQ2d 1429, 1431(Fed Cir 1997).

#### Claim Rejections - 35 USC § 102

8. Claims 9, 16 & 19 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Coughlin et al(U.S. 3,720,321) or Sano et al(U.S. 4,046,843).

Coughlin et al teach semipermeable polymeric membranes formed from polymeric film that includes synthetic polymers such as polymethyl methacrylate. See the Abstract, col. 2, lines 55-58, col. 5, lines 16-29, col. 7, lines 50-66 and the claims of Coughlin et al.

Sano et al teach a semipermeable membrane formed from a mixture of a water-insoluble high polymer and a water-soluble high polymer, a mixture of a water-insoluble high polymer and a water-soluble surfactant or a mixture of a water-insoluble high polymer, a water-soluble high polymer and a water-soluble surfactant wherein the water-insoluble high polymer includes polymethyl methacrylate. See, the Abstract, col. 3, lines 50-57 and the claims, viz. claims 1 & 2 of Sano et al.

Each of Coughlin et al and Sano et al therefore anticipate the instantly claimed invention with the understanding that the semipermeable membranes of Coughlin et al and Sano et al overlap in scope with the claimed semipermeable membrane.

As to the “water transmission” property per claims 9 and 16, it would be expected that the semipermeable membranes of each of Coughlin et al and Sano et al would meet this property limitation since the semipermeable membranes of each Coughlin et al and Sano et al are essentially the same as and made in essentially the same manner as the claimed semipermeable membrane. The onus to prove otherwise is shifted to applicants.

It has been held that where applicant claims a composition in terms of function, property or characteristic where said function is not explicitly shown by the reference and where the examiner has explained why the function, property or characteristic is considered inherent in the prior art, it is appropriate for the examiner to make a rejection under both the applicable section of 35 USC 102 and 35 USC 103 such that the burden is placed upon the applicant to provide clear evidence that the respective compositions do in fact differ. *In re Best*, 195 USPQ 430, 433 (CCPA 1977); *In re Fitzgerald et al.*, 205 USPQ 594, 596 (CCPA 1980).

Even if it turns out that the Examiner has somehow missed the boat and the claims are not anticipated then, it would have been obvious to the skilled artisan to extrapolate, from the disclosures of each of Coughlin et al and Sano et al, the specifically defined semipermeable membrane, as claimed, as per such having been within the purview of the general disclosures of each of patentees and with a reasonable expectation of success, absent a showing of some unusual or unexpected results.

As to the recited “for use in a dosage form” per claim 9, such is considered to be a statement of ultimate intended utility. Moreover, the absence of a disclosure relating to a function does not defeat a finding of anticipation. It is well established that the recitation of a new intended use for an old product does not make a claim to that old product as provided for under the guise of *In re Schreiber*, 128 F 3d 1473, 1477, 44 USPQ2d 1429, 1431(Fed Cir 1997).

9. Applicant's arguments with respect to claims 9 and 16-19 have been considered but are moot in view of the new ground(s) of rejection.

**Conclusion**

10. The additional prior art listed on the FORM PTO 892 is cited as of interest in teaching semipermeable membranes formed from, e.g., cellulosic polymers and considered merely cumulative to the prior art supra.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Judy M. Reddick whose telephone number is (571)272-1110. The examiner can normally be reached on Monday-Friday, 6:30 a.m.-3:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on (571)272-1114. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Judy M. Reddick*  
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Primary Examiner  
Art Unit 1713

JMR *Jmr*  
03/06/04